



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: John A. Krueger Examiner: Jonathan M. Foreman
Serial No.: 10/037,795 Group Art Unit: 3736
Filed: January 3, 2002 Docket No.: SPEC – 6137 / C270.112.101
Due Date: December 16, 2006 (w/ extension)
Title: BONE MARROW ASPIRATION DEVICE WITH CURVED TIP

DECLARATION UNDER 37 C.F.R §1.131 OF JOHN A. KRUEGER

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

I, John A. Krueger, declare as follows:

1. I am the sole-named inventor of the subject matter described and claimed in the above-identified U.S. Patent Application Serial No. 10/037,795 filed January 3, 2002 (“the ‘795 Application”).
2. I make this Declaration in support of the patentability of the claims of the ‘795 Application.
3. This Declaration under 37 C.F.R. §1.131 is made in response to the rejection of claims 6-14 under 35 U.S.C. §103 based on Clark et al., PCT Publication No. WO 01/78590 A1 (“Clark”) having a publication date of October 25, 2001.
4. Prior to the Clark publication date of October 25, 2001, I conceived subject matter of the ‘795 Application. As factual evidence of my conception prior to October 25, 2001, attached hereto is Exhibit A.

Declaration under 37 C.F.R. § 1.131

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5. Exhibit A is a redacted portion of an Invention Record and Assignment Form that I signed on September 20, 2001 relating to the subject matter of the subsequently-filed '795 Application. In connection with the Invention Record and Assignment Form, I prepared and included an inter-office memorandum dated September 6, 2001, a portion of which is included with Exhibit A, in which subject matter of the '795 Application is described in detail. Exhibit A fully supports that subject matter of the '795 Application was conceived prior to October 25, 2001.
6. In or about September 2001, working prototypes of systems incorporating subject matter of the '795 Application were built and tested, as evidenced at page 2 of Exhibit A. It is therefore respectfully submitted that subject matter of the '795 Application was conceived and diligently reduced to practice prior to October 25, 2001.
7. The Invention Record and Assignment Form of Exhibit A was submitted to Allegiance Corporation's in-house patent department in or about September 2001. A non-provisional patent application was subsequently prepared by in-house patent counsel, and was filed on January 3, 2002. Thus, it is respectfully submitted that subject matter of the pending application was also constructively reduced to practice with reasonable diligence.
8. In light of the above, it is respectfully submitted that the '795 Application claims an invention that was conceived prior to October 25, 2001, and diligently reduced to practice. Thus, Clark should be removed as a reference under 35 U.S.C. §103.
9. I further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of

Declaration under 37 C.F.R. § 1.131

Applicant: John A. Krueger

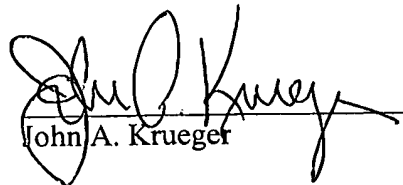
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the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issued thereon.


John A. Krueger

12/15/06
Date

Allegiance Corporation.
McGaw Park, Illinois

RECEIVED

SEP 20 2001

LAW DEPARTMENT



FOR PATENT DEPARTMENT USE ONLY

Invention Record No. *SEC 6137*

**Invention Record and
Assignment Form**

Date 9/6/01	Project No.	Division/Group Special Procedures
This form is for the reporting and assigning to Allegiance any new thing or idea which might be patentable. Submit it to your Department Head or Supervisor, who will forward it to the Intellectual Property Department, Allegiance Corporation, McGaw Park, Illinois. Its purpose is to direct attention to and make a record of new Inventions. The Intellectual Property Department will acknowledge receipt of this form.		
Title of Invention: Coaxial Aspiration Needle for Bone Biopsy Procedure		
Inventor(s) (See Instruction 1). Note: Instructions referred to by number are printed on the Instruction Page.		
Name John A. Krueger	Employee No. 73463	
Residence Milwaukee, Wisconsin	Citizenship USA	
Name	Employee No.	
Residence	Citizenship	
Name	Employee No.	
Residence	Citizenship	
Name	Employee No.	
Residence	Citizenship	
Name	Employee No.	
Residence	Citizenship	
Name	Employee No.	
Residence	Citizenship	

DESCRIPTION OF SUBJECT

The major part of the last two pages have been left blank for description. A suggested outline for the description is included therein. Be sure to explain the subject matter fully.

The following information is desired. Please furnish it if you can. (See Instruction 2).

- A. When did the described subject matter first occur to the inventor(s)? (See Instruction 3).
- B. Was a drawing or sketch made and if so when? (See Instruction 4) Yes ☒ No ☐ Date 9/6/01
- C. When was the first written description of the subject matter (other than this record) made? Date ORIGINAL SUBMISSION OF
Do you have a copy of it? Yes ☒ No ☐ COAXIAL ASPIRATION NEEDLE, THESE ARE FURTHER MODIFICATIONS
- D. On what date was the subject matter first disclosed to others within the Company?
To whom was this disclosure made? GREG GROENKE AND GAWT CLARK
Was it oral or written? ORAL Where was it made? MCGAW PARK, IL
- E. If this subject matter has been described orally or in writing to persons outside of the Company, or samples have been submitted to them, please state the names of such persons and the place and date. Also, please indicate whether the information was provided on a confidential basis.
N/A

- F. Has the thing or idea which you have described in this record been tried experimentally? Yes ☒ No ☐

Used in Company Operations? Yes ☒ No ☐

Disclosed to or discussed with anybody outside the Company? Yes ☒ No ☐

Sold or offered for sale? Yes ☒ No ☐

If any answer is "Yes" state full details on page 2 of this record at place indicated. (See Instruction 6)

- G. Were any funds from government grants or research contracts employed in the development of this subject matter? Yes ☒ No ☐

DETAILED ANSWER TO ITEM F

If the thing or idea described has been tried, used or offered for sale, briefly state here the dates of such trial, where used or to who offered or sold, and the present status.

I TESTED THESE CONCEPTS IN A PIG LAB TO ENSURE DESIGN IMPROVEMENTS ARE EFFECTIVE.

Names of persons who witnessed trial and testing of the subject matter and could, of their own knowledge, testify to what was done.
N/A

Date of first sale of product:
N/A

Please date and sign this document and have two witnesses who can understand its subject matter read it and sign as indicated. In consideration of employment and the salary associated therewith, this invention is hereby assigned to Allegiance Corporation, together with the right to any patents thereon.

Signature of Inventor (Sign in the presence of the witness) Date

X [Signature] 9/20/01
Title PRINCIPAL ENGINEER

Signature of Inventor (Sign in the presence of the witness) Date

X
Title

Signature of Inventor (Sign in the presence of the witness) Date X Title	Signature of Inventor (Sign in the presence of the witness) Date X Title
Signature of Inventor (Sign in the presence of the witness) Date X Title	Signature of Inventor (Sign in the presence of the witness) Date X Title
Signature of Inventor (Sign in the presence of the witness) Date X Title	Signature of Inventor (Sign in the presence of the witness) Date X Title
We have read this Invention Record and Assignment form and understand its subject matter this <u>Sept 20</u> day of <u>2001</u> Signature of Witness X Name (Please Print)	We have read this Invention Record and Assignment form and understand its subject matter this _____ day of _____, 2001 Signature of Witness X Name (Please Print)
APPROVAL OF SUPERVISOR AND DEPARTMENT HEAD Signature X <u>Gregory C. Groenke</u> Name (Please Print) <u>Gregory C. Groenke</u> Title <u>R&D Director</u>	APPROVAL OF SUPERVISOR AND DEPARTMENT HEAD Signature X Name (Please Print) Title

DESCRIPTION OF INVENTION

(The following outline is recommended as a guide for this description. Insert extra page, if necessary.)

- I. Suggested title of invention.
- II. General description of invention.
 - A. General statement of what the invention is.
 - B. Advantages over previous practices in this field and features which distinguish the invention from prior practices.
 - C. Detailed description of the invention. The description should be adequate to provide a full understanding of the invention from this record alone. In mechanical or electrical cases include drawings, sketches or photographs with complete explanation, and use suitable reference numerals or letters to clarify the description. In chemical or process cases give examples in sufficient detail to enable one to carry out the invention. If any of the drawings attached are prints which are too large to be conveniently passed through a standard office photocopying machine, please supply triplicate prints for the convenience of the Patent Department. (If any of the drawings attached are original sketches, or prints of the first drawing of the invention, see Instruction 4.)
 - D. Variants or equivalents of the invention. What alternative approaches would work? How far can conditions and/or reactants be varied from those shown in the specific examples? This information is necessary to determine the scope of the invention.
- III. Notebook number and pages where experimental data is recorded.
- IV. Closest literature (including patents) or prior work of which you are aware. Please supply copies of the literature if it is available to you.

invention not only combines both procedures into one process but it also overcomes the hindrances just discussed. The length in which the coaxial needle extends past the end of the cannula is approximately the same as the length the stylet extends past the end of the cannula. The coaxial aspiration needle is therefore protected from damage.

The end of the coaxial aspiration needle is formed with a curve (Hubber or Weiss type needle tip). This provides an opening 90 degrees to the direction of the bone marrow handle. Therefore the aspirate will be drawn from the side region and not affect the marrow directly below the needle. This is the area in which the marrow core will be taken after the aspiration process is completed. If a dry pocket is found, the coaxial aspiration needle may be rotated 360 degree to see if any other location may have an aspirate. The proximal end of the coaxial aspiration needle has a plastic hub with a luer taper so that the coaxial needle has a sealed junction between the bone marrow handle and the aspiration needle. Therefore, any syringe may be attached to the coaxial aspiration needle to perform the aspiration procedure.

The coaxial aspiration needle is approximately 14 cm in length for the standard 11 gauge DJ. The tube is stainless steel with a plastic hub bonded onto the tube. The plastic hub has an arrow molded into the side of the hub that corresponds to the opening of the coaxial needle. Therefore, the physician will know where the opening of the needle is located. The tube dimensions (ID and OD) and hub are identical to the standard 15 gauge DIN needle.

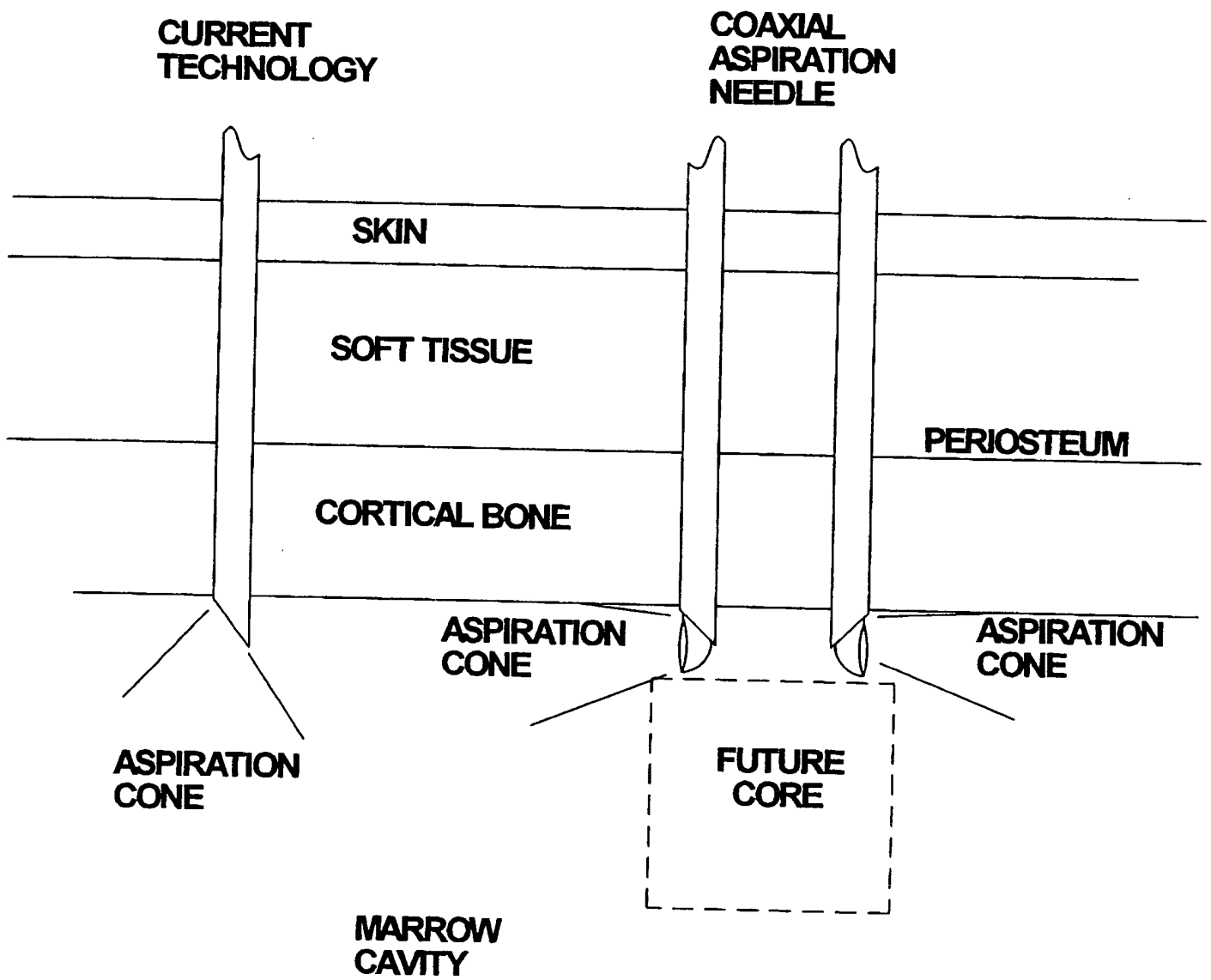


FIGURE 5
COAXIAL
ASPIRATION